



UNITED STATES DEPARTMENT OF COMMERCE  
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08/15/97 402

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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HENRY N. WIXON  
HALE AND DORR  
THE WILLARD OFFICE BUILDING  
1455 PENNSYLVANIA AVENUE NW  
WASHINGTON DC 20004

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EXAMINER
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ART UNIT	PAPER NUMBER
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1806

9-1-98

DATE MAILED:

### INTERVIEW SUMMARY

All participants (applicant, applicant's representative, PTO personnel):

(1) Susan Ungar (3)

(2) Mike Leonard for Henry Wixson

Date of Interview 11/2/97

Type: ☐ Telephonic ☐ Personal (copy is given to: ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No If yes, brief description:

Agreement ☐ was reached. ☐ was not reached.

Claim(s) discussed: All pending

Identification of prior art discussed:

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: The response given

on Aug 6, 1997 to the Country Copy of Restriction Requirement dated Aug 6, 1997 but mailed Aug 7, 1997 has not been entered because the case was lost immediately subsequent to mailing + was recovered only this week when it was discovered that the good faith response was not proper because it responded to the SAKED but not mailed requirement. Therefore the time period for response to the restriction requirement has been reset + is restarted as of 11/2/97. (A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

1. ☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☐ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Examiner Note: You must sign this form unless it is an attachment to another form.

Handwritten signature: Henry Wixson



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08/482,402

APPLICATION NO.	FILING DATE	PAPER NO.	FIRST NAMED INVENTOR	B	ATTORNEY-DOCKET NO.
08/482,402	08/07/95				

18M2/0114

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LINGAR EXAMINER

ART UNIT PAPER NUMBER

01/14/98

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

In view of the telephone interview (see Interview Summary, Paper No. 9) of January 8, 1998, the period for response of 30 days set in the Office Action mailed August 7, 1997 is restarted to begin with the date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731. The fax phone number for this Art Unit is (703) 308-4065.

Communications via Internet e-mail regarding this application, other than those under 35 USC 132 or which otherwise require a signature may be used by the applicant and should be addressed to lila.feisee@uspto.gov.

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of USC 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Susan Ungar  
January 14, 1998

LILA FEISEE  
SUPERVISORY PATENT EXAMINER  
GROUP 1800

received  
1-21-98

Art Unit: 1642

1. The request filed on February 12, 1999 (Paper No. 19) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/482,402 is acceptable and a CPA has been established. Further, the Change of Address and associate power of attorney filed September 23, 1998 (Paper No. 18) is acknowledged and entered. An action on the CPA follows.
2. The Claims 11-15 are pending and currently under examination and claim 37 remains withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions..
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Because all claims are drawn to the same invention claimed in parent application Serial No.08/482,402 and no additional arguments or amendments to the claims have been submitted, claims 11-15 remain rejected for the reasons previously disclosed in Paper No. 17, mailed September 15, 1998 as follows:
5. It is noted that Applicant regrets Examiner's decision to make the Restriction Requirement final and restates the arguments previously disclosed. The arguments have been noted but have not been found persuasive for the reasons previously disclosed on page 2 in both Paper Nos 8 and 12. Applicant further argues that (a) there is no logical or technical basis for requiring the restriction of claims designated in the parent application as falling within a single Examiner-identified Group and (b) all of the claims in Group IV share Class and Subclass designations therefore search and examination of the entire Group can be made without serious burden. The arguments have been noted but have not been found persuasive because (a) of the logical and technical reasons disclosed in Paper No. 8, Section 2, page 2 and

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demonstrate the immunological and enzymatic activity of the soluble hTPO (see pages 58-60) there are no parameters described and no teaching of how to determine which sites are appropriate for mutation so that DNA sequences could be made and then selected for testing and evaluation to determine if the mutated, expressed protein will be soluble and function as claimed. The single example of a mutated thyroid peroxidase is not sufficient enablement for Applicant's broadly claimed invention. The claims as broadly written appear to be an invitation to experiment. Applicant's attention is directed to Brenner v. Manson, 383, U.S. 519, 148 USPQ 689 wherein the court held that "a patent is not a hunting license". Applicant's arguments have not been found persuasive and the rejection is maintained.

11. Claims 11-15 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As drawn to (b), Applicant argues that the language is definite and will be understood by a person of ordinary skill. The argument has been noted but has not been found persuasive for the reasons previously disclosed in Paper No. 12, Section 13, page 7. The rejection of the claim can be obviated by amending the claim to read "A recombinant DNA sequence encoding a human thyroid peroxidase.....".

***Claim Rejections - 35 USC § 103***

12. Claims 11-15 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 12, Section 16, pages 9-11.

Applicant argues that (a) none of the secondary references satisfy the failings of the primary references and that none of the references, alone or in combination

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provides the suggestion to combine required to state a proper *prima facie* obviousness rejection and (b) Examiner has used improper hindsight to supply the missing suggestion to combine which Examiner has not found in any of the primary or secondary references. The argument has been noted but has not been found persuasive because Applicant has not presented any arguments to explain why the secondary references do not satisfy the failings of the primary reference or why none of the references alone or in combination provides the suggestion to combine required to state a proper *prima facie* obviousness rejection. (b) Some degree of hindsight is permissible in making rejections under 35 USC 103, however, at the time the invention was made <sup>(1)</sup> (a) the DNA sequence of human thyroid peroxidase was well known as demonstrated by Seto and Libert, <sup>(2)</sup> (b) the production of secreted proteins by transfecting host CHO cells with cDNA encoding truncated protein (wherein the hydrophilic carboxyl-terminus is deleted) and the advantages of secreted proteins were well known as demonstrated by EP 0139417 and Rose et al, © structural analysis of porcine thyroid peroxidase revealed a carboxyl-terminal transmembrane domain consistent with the cellular location of a putative membrane anchor as demonstrated by Magnusson et al, (d) expression vectors were well known as demonstrated by Lee et al and Ellis et al. Clearly the combined references teach not only the suggestion but also the means and motivation to successfully produce a recombinant DNA encoding a secretable thyroid peroxidase for the reasons disclosed in Paper No.12, Section 16, page 10. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the

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combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

13. All other objections and rejections recited in Paper No. 12 are withdrawn.

14. No claims allowed.

15. This is a CPA of applicant's earlier application S.N. 08/482,402. All claims are drawn to the same invention claimed in the earlier application and, although applicant has filed request for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d), no Amendment or Response containing either arguments drawn to the instant rejections or amendments to the claims has been submitted. Thus, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). See M.P.E.P. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

14. Any inquiry concerning this communication or earlier communications from

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the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

March 4, 1999

  
PAULA K. HUTZELL  
SUPERVISORY PATENT EXAMINER